



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket Nos. FDA-2007-0601, FDA-2004-N-0382, FDA-2005-P-0371, and FDA-2006-P-0224 (formerly Docket Nos. 2004N-0217, 2005P-0189, and 2006P-0137, respectively)]

RIN 0910-ZA28

Food Labeling: Nutrient Content Claims; Alpha-Linolenic Acid, Eicosapentaenoic Acid, and Docosahexaenoic Acid Omega-3 Fatty Acids

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is issuing this rule to prohibit certain nutrient content claims for foods, including conventional foods and dietary supplements, that contain omega-3 fatty acids, based on our determination that such nutrient content claims do not meet the requirements of the Federal Food, Drug, and Cosmetic Act (the FD&C Act). We are taking this action in response to three notifications submitted to us. One notification concerning nutrient content claims for alpha-linolenic acid (ALA), docosahexaenoic acid (DHA), and eicosapentaenoic acid (EPA) was submitted collectively by Alaska General Seafoods, Ocean Beauty Seafoods, Inc., and Trans-Ocean Products, Inc. (the seafood processors notification); a second notification concerning nutrient content claims for ALA, DHA, and EPA was submitted by Martek Biosciences Corp. (the Martek notification); and a third notification concerning nutrient content claims for DHA and EPA was submitted by Ocean Nutrition Canada, Ltd. (the Ocean Nutrition notification). The final rule prohibits the nutrient content claims for

DHA and EPA set forth in the three notifications and the nutrient content claims for ALA set forth in the seafood processors notification. FDA is taking no regulatory action at this time with respect to the nutrient content claims for ALA set forth in the Martek notification and, therefore, these claims will be allowed to remain on the market.

DATES: This rule is effective January 1, 2016.

FOR FURTHER INFORMATION CONTACT: Vincent de Jesus, Center for Food Safety and Applied Nutrition (HFS-830), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1774.

SUPPLEMENTARY INFORMATION:

I. Background

The Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105-115) amended the FD&C Act to provide, among other things, for the filing of notifications as an alternative to the petition process for nutrient content claims set forth in section 403(r)(4) of the FD&C Act (21 U.S.C. 343(r)(4)). “Nutrient content claims” are labeling claims that characterize the level of a nutrient in a food. (See section 403(r)(1)(A) of the FD&C Act.) We have stated that the Nutrition Labeling and Education Act of 1990 (Pub. L. 101-535), which created section 403(r)(1)(A) of the FD&C Act, has three basic objectives: (1) To make available nutrition information that can assist consumers in selecting foods that can lead to healthier diets, (2) to eliminate consumer confusion by establishing definitions for nutrient content claims that are consistent with the terms defined by the Secretary of Health and Human Services (the Secretary), and (3) to encourage product innovation through the development and marketing of nutritionally improved foods (58 FR 2302, January 6, 1993). Under the notification process that FDAMA established in section 403(r)(2)(G) of the FD&C Act, a nutrient content claim is based on an

authoritative statement published either by a scientific body of the U.S. Government that has official responsibility for public health protection or research directly relating to human nutrition, or by the National Academy of Sciences (NAS) or any of its subdivisions.

Section 403(r)(2)(G) of the FD&C Act requires that a notification for a prospective nutrient content claim be submitted to FDA at least 120 days before a food bearing the claim may be introduced into interstate commerce. The notification must contain specific information including: (1) The exact wording of the prospective nutrient content claim, (2) a concise description of the basis upon which the notifier relied for determining that the requirements for an authoritative statement in section 403(r)(2)(G)(i) of the FD&C Act have been satisfied, (3) a copy of the authoritative statement that serves as the basis for the claim, and (4) a balanced representation of the scientific literature relating to the nutrient level for the claim. The claim must be an accurate representation of the authoritative statement and must be stated in a manner that enables the public to comprehend the information provided by the claim and to understand the relative significance of such information in the context of the total daily diet. Furthermore, the authoritative statement that is the basis for the nutrient content claim must be currently in effect and identify the nutrient level to which the claim refers.

In the Federal Register of November 27, 2007 (72 FR 66103), we published a proposed rule that would prohibit all of the nutrient content claims for the omega-3 fatty acids DHA and EPA set forth in: (1) The seafood processors notification submitted on January 16, 2004, (2) the Martek notification submitted on January 21, 2005, and (3) the Ocean Nutrition notification submitted on December 9, 2005. The seafood processors notification set forth “high”¹ nutrient

¹ Nutrient content claims are defined in § 101.54 (21 CFR 101.54). “High” is defined as 20 percent or more of the Reference Daily Intake (RDI) or the Daily Reference Value (DRV) per reference amount customarily consumed (RACC) (§ 101.54(b)). “Good source” is defined as 10 to 19 percent of the RDI or DRV per RACC (§ 101.54(c)).

content claims for both DHA and EPA,² whereas the Martek notification set forth a “high” nutrient content claim only for DHA³ and the Ocean Nutrition notification set forth a “high” nutrient content claim for DHA and EPA combined.⁴ The proposed rule would take this action because the nutrient content claims for DHA and EPA set forth in the three notifications are not based on an authoritative statement that identifies a nutrient level to which the claims refer, as required by the FD&C Act.

The proposed rule also would prohibit the nutrient content claims for ALA set forth in the seafood processors notification⁵ because the claims were based on a reference value that was determined by a different approach than reference values already established for other nutrients (i.e., Daily Values (DV)). In the report entitled “Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids” from the Institute of Medicine (IOM) of the NAS (“the IOM report”) (Ref. 1), the IOM identified several age-gender group specific adequate intake levels (AIs) for ALA, including 1.6 grams per day (g/day)

“More” is defined as 10 percent or more of the RDI or DRV per RACC than an appropriate reference food (§ 101.54(e)). Synonyms for each of these terms are also set forth in the regulations; for example, the terms “rich in” and “excellent source of” are considered to be equivalent to the term “high” (§ 101.54(b)).

² The seafood processors notification specified that one of the following two statements would accompany these claims:

“Contains ___ mg of [DHA/EPA] per serving, which is ___ % of the Daily Value for [DHA/EPA] (130 mg).”

“Contains ___ % of the Daily Value for [DHA/EPA] per serving. The Daily Value for [DHA/EPA] is 130 mg.”

As indicated in the notification, use of [DHA/EPA] is intended to mean that either EPA or DHA can be used as the subject of the claim.

³ The Martek notification proposed the following exact wording for these claims: “ ‘Excellent source of DHA.’ (‘High in DHA,’ ‘Rich in DHA’) Contains ___ mg of DHA per serving, which is ___ % of the 160 mg Daily Value for DHA.” [Products would need to contain at least 32 mg of DHA per RACC to qualify for the claim.]

⁴ The Ocean Nutrition notification proposed the following exact words for these claims: “ ‘Excellent source of Omega-3 EPA and DHA.’ (‘High in Omega-3 EPA and DHA,’ ‘Rich in Omega-3 EPA and DHA’). Contains ___ mg of EPA and DHA combined per serving, which is ___ % of the 160 mg Daily Value for a combination of EPA and DHA. ” FDA notes that this claim language was incorrectly written in the proposed rule, where it was written as “ ‘Excellent source of Omega-3 EPA and DHA.’ (‘High in Omega-3 EPA and DHA,’ ‘Rich in Omega-3 EPA and DHA’). Contains ___ mg of EPA and DHA combined per serving, which is ___ % of the 160 mg EPA and DHA combined per serving, which is ___ % of the 160 mg Daily Value for a combination of EPA and DHA. ”

⁵ The seafood processors notification proposed “high,” “good source,” and “more” claims for ALA. The notification specified that one of the following two statements would accompany “high” and “good source” claims for ALA:

“Contains ___ mg of ALA per serving, which is ___ % of the Daily Value for ALA (1.3 g).”

“Contains ___ % of the Daily Value for ALA per serving. The Daily Value for ALA is 1.3 g.”

for males 14 and more years of age and 1.1 g/day for females 14 and more years of age. (See also 72 FR 66103 at 66106.) The seafood processors calculated a population-weighted AI to use as the reference value for their claims. This approach differs from our approach, under which reference values are set by using the population-coverage approach. (See 58 FR 2206 at 2210 through 2211, January 6, 1993.) Under a “population-coverage approach,” we would use the highest Recommended Daily Allowance (RDA) or AI for adults and children 4 or more years of age (excluding values for pregnant and lactating women) to serve as the label reference value. (See, e.g., 72 FR 62149 at 62150, November 2, 2007.) In contrast, the seafood processors calculated a population-weighted reference value--they looked at the various AIs that the IOM identified for different age and gender groups (excluding children under 4 years of age and pregnant and lactating women) and averaged out all of those numbers, taking into account the predominance of the various groups within the population, to arrive at their label reference value. The difference, in brief, is that we essentially take the highest number to use as the label reference value, while the seafood processors would take an average of the various numbers to use as their reference value.

In the proposed rule, we tentatively determined that the seafood processors notification’s use of a different methodology to set the reference values does not enable the public to comprehend the information provided in the ALA claim and to understand the relevant significance of such information in the context of the daily diet. We indicated that we would not take regulatory action at this time on the ALA claims set forth in the Martek notification,⁶ which

⁶ The Martek notification proposed “high,” “good source,” and “more” claims for ALA. The notification proposed the following exact words for these claims:

“ ‘Excellent source of ALA.’ (‘High in ALA,’ ‘Rich in ALA’) Contains ____ mg of ALA per serving, which is ____ % of the 1.6 g Daily Value for ALA.” [Products would need to contain at least 320 mg of ALA per RACC to qualify for the claim.]

used a population-coverage approach that is consistent with the approach that FDA has used in determining DVs to date (see 58 FR 2206 at 2211). We expressed no conclusions as to whether the ALA claims in the Martek notification are supported by an authoritative statement that satisfies the requirements of section 403(r)(2)(G) of the FD&C Act. Because the proposed rule would neither prohibit nor modify the nutrient content claims for ALA set forth in the Martek notification, we indicated that we would allow these claims to remain on the market at this time (see 72 FR 66103 at 66104).

II. Summary of Comments and Agency's Responses

We invited comments on the proposed rule. The comment period closed on February 11, 2008. We received 19 comments, each containing one or more issues. The comments were from manufacturers, trade associations, and health-related organizations. One comment raised issues that were outside the scope of this rulemaking, and we will not discuss it in this document. We discuss the remaining comments and our responses in part II. For ease of reading, we preface each comment discussion with a numbered "Comment," and each response by a corresponding numbered "Response." We have numbered each comment to help distinguish among different topics. The number assigned is for organizational purposes only and does not signify the comment's value, importance, or the order in which it was received.

(Comment 1) Several comments stated that the nutrient content claims for DHA and EPA should be permitted because the statements from the IOM report that were used as the basis for

“ ‘Good source of ALA.’ (‘Contains ALA,’ ‘Provides ALA’) Contains ____ mg of ALA per serving, which is ____ % of the 1.6 g Daily Value for ALA” [Products would need to contain at least 160 mg of ALA per RACC to qualify for the claim.]

“ ‘More ALA.’ (‘Fortified with ALA,’ ‘Enriched with ALA,’ ‘Added ALA,’ ‘Extra ALA,’ ‘Plus ALA’) Contains ____ % more of the Daily Value for ALA per serving than [reference food]. This product contains ____ mg of ALA which is ____ % of the Daily Value for ALA (1.6 g).” [Products would need to contain at least 160 mg or more ALA per RACC than an appropriate reference food and would comply with the requirements for relative claims found at 21 CFR 101.13(j).]

these claims are authoritative statements that identify a nutrient level, as required by the statute.

Specifically, the comments pointed to the following statements from the IOM report:

- [EPA] and [DHA] contribute approximately 10 percent of the total n-3 fatty acid intake and therefore this percent contributes toward the AI for [ALA].
- Small amounts of EPA and DHA can contribute towards reversing an n-3 fatty acid deficiency...and can therefore contribute toward the AI for [ALA]. EPA and DHA contribute approximately 10 percent of the total n-3 fatty acid intake and therefore this percent contributes toward the AI for [ALA].
- The AMDR[Acceptable Macronutrient Distribution Range] for [ALA] is set at 0.6 to 1.2 percent of energy. Ten percent of this range can be consumed as [EPA] and/or [DHA].
- Approximately 10 percent of the AMDR for n-3 fatty acids ([ALA]) can be consumed as EPA and/or DHA (0.06 to 0.12 percent of energy).

The comments asserted that these statements permit a calculation of a value for DHA and EPA that can be considered a “nutrient level.” The comments further asserted that our position regarding the term “nutrient level” goes beyond what the statute requires and is unduly restrictive. These comments characterized our position as interpreting the term “nutrient level” to refer to reference values that are similar in type to Dietary Reference Intakes (DRI) or other types of defined intake levels that serve as reference values for the basis of nutrient content claims. Based on these contentions, the comments asserted that the proposed rule was contrary to Congressional intent in that we are imposing standards of traditional rulemaking on a process that Congress intended to be an expedited process of information dissemination. If Congress had intended otherwise, at least one comment stated, it could have explicitly indicated that a specific type of reference value be required; however, Congress did not do so.

(Response) We disagree. We consider the term “nutrient level” as used in section 403(r)(2)(G)(i) of the FD&C Act, to mean a reference value that is similar to a label reference value for use in nutrition labeling, i.e., that reflects a recommended or defined intake level that could serve as a basis for setting a DV that could be used to characterize a given level of a nutrient (here, DHA or EPA) for purposes of nutrition labeling. To date, our regulations have established two types of DVs: RDIs and DRVs (72 FR 66103 at 66104 through 66105). However, contrary to what some comments suggest, the proposed rule would not have the statutory term “nutrient level” refer only to RDIs and DRVs. Instead, we proposed that the term refers to values that could serve as a basis for setting a DV, in that they could be used to characterize a given level of a nutrient for the purposes of nutrition labeling (72 FR 66103 at 66109). DVs are intended to help consumers understand the relative significance of information about the amount of certain nutrients in a food in the context of a total daily diet and to help consumers compare the nutritional values of food products. Permitting nutrient content claims on the basis of statements that do not identify the nutrient level to which the claims refer results in inconsistent and conflicting claims that can confuse consumers. Congress required that an authoritative statement identify the “nutrient level to which the claim refers” (section 403(r)(2)(G) of the FD&C Act) to help ensure consistency among different products from different manufacturers.

Our use of “nutrient level” to mean a reference value that reflects a recommended or defined intake level that could serve as a basis for setting a DV is in keeping with the plain meaning of the word “level,” both alone and in the statutory context in which the term is used. The Oxford English Dictionary defines “level” in relevant part as, “A position (on a real or imaginary scale) in respect of amount, intensity, extent, or the like; the relative amount or

intensity of any property, attribute, or activity. Freq. preceded by a sb. denoting the property, etc., referred to, as danger, energy, noise level.” (See Level Definition, The Oxford English Dictionary (Second Edition 1998) (emphasis in the original).) Section 403(r)(2)(G) of the FD&C Act states, in relevant part: “A claim of the type described in subparagraph (1)(A) for a nutrient...shall be authorized and may be made with respect to a food if...a scientific body...has published an authoritative statement...which identifies the nutrient level to which the claim refers.” The word “level” is preceded by the word “nutrient” to denote the property referred to. The nutrient level serves to identify “[a] position...in respect of amount,” in the words of the dictionary definition; in other words, the authoritative statement must identify a specific amount of the nutrient in question. This nutrient level is the thing “to which the claim refers,” and our use of the “nutrient level” as a reference value is consistent with the plain meaning. The statutory phrase “the nutrient level” indicates that a single, precise nutrient level must be identified by the authoritative statement.

Moreover, the meaning of the phrase “nutrient level” is further clarified by the statutory context in which the phrase appears, as well as related statutory provisions regarding how nutrient content claims function. Section 403(r)(2)(G) of the FD&C Act describes one way that claims “of the type described in [403(r)(1)(A)]” can be made. The type of claim described in section 403(r)(1)(A) of the FD&C Act is a claim that “characterizes the level of any nutrient...,” i.e., a nutrient content claim. Such claims characterize the specific amount of a nutrient that is found in one serving of a specific product by using terms such as “good source.” In general, such claims can only be made “if the characterization of the level made in the claim uses terms which are defined in regulations of the Secretary.” (Section 403(r)(2)(A)(i) of the FD&C Act.) We defined terms such as “good source” in a way that ties each term’s meaning to the DV that has

been established by regulation for the nutrient in question--for example, “good source” claims can be made for foods that contain 10 to 19 percent of the DV for the relevant nutrient per reference amount customarily consumed (§ 101.54(c)). With respect to “a nutrient, for which the Secretary has not promulgated a regulation,” Section 403(r)(2)(G) of the FD&C Act allows for the possibility that a nutrient content claim can still be made, if an authoritative statement “identifies the nutrient level to which the claim refers.” We do not require that this nutrient level be an RDI or a DRV, but the nutrient level must be a single reference value or else it would be impossible to know when the definition for a term such as “good source” had been met. Moreover, for a nutrient content claim to provide a meaningful characterization of the level of the nutrient, the reference value must be such that it helps consumers understand the relative significance of information about the amount of the nutrient in a food in the context of a total daily diet; Congress emphasized the importance of this goal in section 403(r)(2)(G)(iv) of the FD&C Act. We have determined that a reference value that reflects a recommended or defined intake level that could serve as a basis for setting a DV serves this purpose and is a “nutrient level.” Therefore, the meaning of “nutrient level” in section 403(r)(2)(G)(i) of the FD&C Act is a reference value that is similar to a label reference value for use in nutrition labeling, i.e., that reflects a recommended or defined intake level that could serve as a basis for setting a DV that could be used to characterize a given level of a nutrient for purposes of nutrition labeling.

According to section 403(r)(2)(G)(i) of the FD&C Act, an authoritative statement that identifies the nutrient level to which the claim refers can be provided by a scientific body of the U.S. Government with official responsibility for public health protection or research directly relating to human nutrition or the NAS or any of its subdivisions, such as the IOM. The IOM provides authoritative statements on recommended or defined nutrient intake levels in the form

of DRIs. DRIs include the Estimated Average Requirement, RDA, AI, and Tolerable Upper Intake Level. The IOM report does not establish any of these for DHA and EPA. The statements in the IOM report that use the terms “approximately 10 percent” do not identify a nutrient level for DHA and/or EPA. The statements describe the approximate contribution that DHA and EPA can make toward meeting the AI for ALA, but they do not reflect a recommended or defined intake level of DHA and/or EPA that could serve as a basis for setting a DV that could be used to characterize a given level of DHA and/or EPA. In fact, the three notifications reflect different readings of the IOM’s statement: the seafood processors notification states that 10 percent of their proposed reference value for ALA results in a reference value for DHA or EPA; the Ocean Nutrition notification states that 10 percent of its proposed reference value for ALA results in a reference value for EPA and DHA combined; and the Martek notification states that 10 percent of its proposed reference value for ALA results in a reference value for DHA alone. (The three notifications also differ in that the Martek notification and the Ocean Nutrition notification conclude that 160 milligrams (mg)/day is the nutrient level that is obtained by dividing by 10, while the seafood processors notification arrives at 130 mg/day, also by dividing by 10. This difference stems from a dispute as to whether 1.6 g/day is the appropriate nutrient level to use in nutrient content claims for ALA, or whether 1.3 g/day is the appropriate level. Because we find that none of the submitted claims for DHA and/or EPA is based on an authoritative statement that identifies a nutrient level for DHA and/or EPA, we do not reach the issue of addressing this discrepancy in the numbers.) The discrepancy in how the three notifications read the IOM’s statements underscores the fact that the statements in the IOM report do not identify a nutrient level for DHA or EPA. Moreover, the statements in the IOM report are explicitly approximate, whereas the statutory and regulatory structure requires that a “nutrient level” be a single, precise

reference value. Finally, we note that these statements do not appear to meet the National Research Council Governing Board of NAS' definition of an authoritative statement, in that they do not "appear explicitly as findings, conclusions, or recommendations" (see Docket No. FDA-2004-N-0382) (Ref. 2)).

We note that nutrient content claims may be based on authoritative statements from various sources and are not limited to authoritative statements from the IOM. Authoritative statements on defined nutrient intake levels from the IOM are provided in the form of DRIs and are only one source of such statements. Authoritative statements from other entities described in section 403(r)(2)(G)(i) of the FD&C Act that include nutrient levels that reflect a recommended or defined intake level that could serve as a basis for setting a DV also may be used as the basis for nutrient content claims. Absent such a statement, the FD&C Act allows interested persons to submit a petition for a nutrient content claim (section 403(r)(4) of the FD&C Act; 21 CFR 101.69).

(Comment 2) Several comments asserted that the FD&C Act does not require us to use a specific approach to determine a reference nutrient value (i.e., population-coverage versus population-weighted). One comment noted that IOM recommended the use of a population-weighted approach for setting nutrient references values in its 2003 report entitled "Dietary Reference Intakes: Guiding Principles for Nutrition Labeling and Fortification" (hereinafter "the IOM report on Guiding Principles") (Ref. 3). Finally, the comments requested that we not act on current ALA nutrient content claims until after completing the rulemaking initiated by our Advance Notice of Proposed Rulemaking (ANPRM) on the Revision of Reference Values and Mandatory Nutrients (72 FR 62149) ("DV ANPRM") which sought public comment on what

new reference values we should use to calculate the DVs in the Nutrition Facts label and what factors we should consider in establishing these new reference values.

(Response) We disagree with the comments. The FD&C Act requires that a claim based on an authoritative statement have a nutrient level identified in the statement and be stated in a manner that enables the public to comprehend the information provided and to understand the relative significance of such information in the context of the daily diet (section 403(r)(2)(G)(iv) of the FD&C Act). Using two different approaches to set a reference value for ALA (i.e., the population-weighted approach used in the seafood processors notification and the population-coverage approach used in the Martek notification) will result in inconsistent and conflicting nutrient content claims on food labels. Such inconsistencies make meaningful product-to-product comparisons impossible. To enable the public to comprehend the information provided in nutrient content claims and to understand the relative significance of that information in the context of the daily diet, as required by section 403(r)(2)(G)(iv) of the FD&C Act, qualifying ALA levels for nutrient content claims in food labeling must be based on a single nutrient value determined using the same approach for reference values for other nutrients, which is currently the population-coverage approach established in the 1993 final rule for determining DVs (58 FR 2206). Therefore, to prevent inconsistent and conflicting claims on food labels, we are not taking regulatory action at this time with respect to ALA claims based on the population-coverage approach, but are prohibiting claims based on the population-weighted approach.

We also disagree that we should not act on current ALA nutrient content claims until we have completed the rulemaking initiated by the DV ANPRM. The concurrent use of two different approaches to set a reference value for ALA will result in inconsistent and conflicting nutrient content claims on food labels. Because it may be some time before any rulemaking

related to the DV ANPRM is finalized, we are taking action now to prevent inconsistent and conflicting claims by prohibiting ALA claims based on the population-weighted approach.

(Comment 3) Several comments asserted that nutrient content claims constitute commercial speech and that, by not allowing the claims to appear on labeling, we would violate the First Amendment. One comment also noted, with respect to the claims regarding DHA and EPA, that we have not done an analysis on each claim to determine if the claims we propose to prohibit would be misleading and whether they could be cured by disclaimers, nor have we identified any safety concerns or provided evidence of consumers being misled by these nutrient content claims. Moreover, a number of comments stated that the FD&C Act allows us to modify claims to provide more information regarding the basis of the claims (for example through use of a disclosure or disclaimer) if any of the claims are found to be misleading, yet we have not done so. For all of these reasons, the comments asserted that prohibiting these claims could violate the First Amendment.

(Response) FDA disagrees. As the preamble to the proposed rule explained (72 FR 66103 at 66104), the 1993 regulations that implemented the Nutrition Labeling and Education Act of 1990 (NLEA) created a procedure under which a person who wishes to make a nutrient content claim not already defined by regulation may petition us to authorize that claim under section 403(r)(4) of the FD&C Act (§ 101.69). Under that process, the petitioner must set forth an explanation of the reasons why the proposed claim meets the requirements of the FD&C Act and a summary of the scientific data supporting those reasons. (See section 403(r)(4)(B) of the FD&C Act.) We can either deny the petition or issue a proposed rule to take the action requested in the petition. If we issue a proposed rule, the rulemaking must be completed within 540 days of the date the petition was received. (See section 403(r)(4)(A)(i) of the FD&C Act.) The U.S.

Court of Appeals for the Second Circuit upheld this statutory scheme and our implementation of it as constitutional. Nutritional Health Alliance v. Shalala, 144 F.3d 220 (2d Cir. N.Y. 1998).

FDAMA created an alternate, expedited notification process to allow certain nutrient content claims to be made without going through the petition process. (See H. Rept. 105-306 (1997) (“It is the Committee’s intention that the FDA will use this authority primarily for the purpose of expediting review of petitions for health and nutrient content claims based on authoritative statements.”).) When the requirements of FDAMA’s expedited notification process (as set out in section 403(r)(2)(G) of the FD&C Act) have been met, the claim can be made; preapproval by FDA is not required. If the requirements of section 403(r)(2)(G) of the FD&C Act have not been met, FDAMA’s expedited path is not available. In such situations, the petition process outlined under section 403(r)(4) of the FD&C Act is the proper vehicle for submitting a proposed nutrient content claim to us. (See H. Rept. 105-306 (1997) (“The Committee emphasizes that this provision maintains the full range of existing FDA enforcement powers with respect to claims made in violation of the statutory requirements.”).)

The petition process set forth in section 403(r)(4) of the FD&C Act relates only to two types of labeling claims: “nutrient content claims,” which are claims of the type described in section 403(r)(1)(A) of the FD&C Act; and “health claims,” which are claims of the type described in section 403(r)(1)(B) of the FD&C Act. FDAMA’s alternate, expedited route also applies only to these two types of claims. (See sections 403(r)(2)(G) through (r)(2)(H) and 403(r)(3)(C) through (r)(3)(D) of the FD&C Act.) (This rulemaking concerns only nutrient content claims.) There are numerous other types of claims that can be made on food and supplement labeling, including many types of claims that can lawfully be made about the presence of DHA or EPA. (See 72 FR 66103 at 66109.) Under § 101.13(i)(3) (21 CFR

101.13(i)(3)), the label or labeling of a food may contain a statement about the amount or percentage of a nutrient if the statement does not, explicitly or implicitly, characterize the level of the nutrient in the food and is not false or misleading in any respect. For example, a conventional food or a dietary supplement may bear a statement such as “X mg of EPA and DHA omega-3 fatty acids per serving.” Also, under § 101.13(q)(3)(ii)(A), dietary supplements are permitted to bear simple percentage claims (e.g., 40 percent EPA and DHA omega-3 fatty acids), and under 21 CFR 101.14(q)(3)(ii)(B), they are permitted to bear comparative percentage claims (e.g., “four times the EPA and DHA omega-3 fatty acids per capsule (80 mg) as in 100 mg of menhaden oil (20 mg)”). Furthermore, in 2003, we announced our intention to exercise our enforcement discretion with respect to the following qualified health claim, which companies can use to describe to consumers the potential health benefits of consuming EPA and DHA: “Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease. One serving of [name of food] provides [x] grams of EPA and DHA omega-3 fatty acids. [See nutrition information for total fat, saturated fat and cholesterol content.]” See Letter Responding to Health Claim Petition dated November 3, 2003 (Martek Petition): Omega-3 Fatty Acids and Reduced Risk of Coronary Heart Disease (Docket No. 2003Q-0401) (available at <http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm072932.htm>); see also Letter Responding to Health Claim Petition dated June 23, 2003 (Wellness petition): Omega-3 Fatty Acids and Reduced Risk of Coronary Heart Disease (Docket No. 2003Q-0401) (available at <http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm072936.htm>).

Section 403(r)(2)(G) of the FD&C Act takes place within this broader labeling context. Nutrient content claims, such as the ones about DHA, EPA, and ALA that the notifiers here seek to make, are just one, very specific, statutorily-defined type of labeling claim. When a company wishes to make such a claim about a nutrient for which FDA has not identified a nutrient level, the company generally must use the process set forth in section 403(r)(4) of the FD&C Act; this process has been upheld as constitutional. (See Nutritional Health Alliance v. Shalala, 144 F.3d 220 (2d Cir. N.Y. 1998).) FDAMA creates an alternate, expedited route, but only in situations where all of the requirements of section 403(r)(2)(G) of the FD&C Act have been met.

Our application of section 403(r)(2)(G) of the FD&C Act to the notifications concerning EPA and DHA and the notifications concerning ALA is constitutional, as explained herein:

A. DHA and EPA

With respect to the proposed claims regarding DHA and EPA, our response to comment 1 explains that the notifiers have not met the requirement of section 403(r)(2)(G)(i) of the FD&C Act that each proposed claim be based on an authoritative statement that identifies a nutrient level to which the proposed claim refers. We therefore find that these claims may not be used in food labeling.

When we establish by regulation particular definitions for terms (such as “good source”), the use of such terms without complying with the established definitions is inherently misleading, and therefore not protected by the First Amendment, see Central Hudson Gas & Elec. Corp. v. Public Serv. Comm’n of New York, 447 U.S. 557, 563 (1980); see also In re R.M.J., 455 U.S. 191, 203 (1982), because such use implies that the definitions and other statutory and regulatory requirements have been met, which they have not. See, e.g., Am. Acad. of Pain Mgmt v. Joseph, 353 F.3d 1099, 1108 (9th Cir. 2004) (finding that the use of the term

“board certified” is inherently misleading when its use does not conform to the statutory definition of that term); see also United States v. Articles of Food * * * Clover Club Potato Chips, 67 F.R.D. 419, 424 (D. Idaho 1975) (“Freedom of [s]peech does not include the freedom to violate the labeling provisions of the Federal Food, Drug, and Cosmetic Act.”). Furthermore, insofar as the proposed claims state or imply that a daily value for DHA or EPA has been established, the claims are false, and are not afforded First Amendment protection. See Central Hudson, 447 U.S. at 563; see also In re R.M.J., 455 U.S. at 203.

The comments seem to suggest that, even if we find that the proposed DHA and EPA claims are not based on an authoritative statement that identifies a nutrient level as required by statute, the First Amendment nonetheless requires us to allow the claims to appear and to use a disclaimer to cure the flaw. The comments did not indicate what the disclaimer would be, and indeed, we conclude that there is no disclaimer that could cure the fundamental flaw of the proposed DHA and EPA claims: namely, that the claims are not based on an authoritative statement that identifies a nutrient level, as required by statute. Cf. Wallach v. Crawford, 2005 U.S. Dist. LEXIS 43700 (S.D. Cal. Mar. 29, 2005) (“A disclaimer regime simply cannot provide the same protection that Congress envisioned....”). One comment seemed to suggest that consumer research could help identify an appropriate disclaimer. However, the statute does not permit the use of FDAMA’s expedited process unless an authoritative statement identifying a nutrient level has been made. We have concluded that the statutory threshold has not been met, and that these claims cannot be permitted under the FD&C Act. These conclusions are not amenable to further exploration through consumer research. Cf. Alliance for Natural Health U.S. v. Sebelius, 786 F.Supp.2d 1, 14 (D.D.C. 2011) (“Pearson [v. Shalala], 164 F.3d 650 (D.C. Cir. 1999)] does not require the FDA to make an empirical showing of the inefficacy of a disclaimer

before prohibiting a claim” that is “unprotected commercial speech that can be prohibited under the threshold step of the Central Hudson analysis.”).

B. ALA

One comment stated that we would violate the First Amendment by prohibiting the ALA claims proposed in the seafood processors notification.

We disagree. Under section 403(r)(2)(G)(iv) of the FD&C Act, “The claim must be an accurate representation of the authoritative statement and must be stated in a manner that enables the public to comprehend the information provided by the claim and to understand the relative significance of such information in the context of the total daily diet.” (See section 403(r)(2)(G)(iv) of the FD&C Act.) As we discussed in more detail under Comment 2, we have determined that the proposed ALA claims that are based on population-weighted AIs do not enable the public to understand the claims’ relative significance in the context of the total daily diet because using two different approaches to set a reference value for ALA will result in inconsistent and conflicting nutrient content claims on food labels. The claims therefore do not conform to the requirements of the FD&C Act and, like the DHA and EPA claims discussed previously, cannot be made.

Furthermore, the ALA claims that are based on population-weighted AIs are inherently misleading, and thus not entitled to First Amendment protection, see Central Hudson, 447 U.S. at 563, and In re R.M.J., 455 U.S. at 203, because the use of two different daily values for ALA would result in inconsistent and contradictory nutrient content claims. Consumers cannot make meaningful product-to-product comparisons based on such claims.

The ALA claims take place against a backdrop where all other food labeling references to nutrient levels are based on the population-coverage approach. In most situations, the reference

value that results from the population-coverage approach will be higher than the reference value that results from the population-weighted approach; thus, by using the latter method, a company can in effect hold itself to a lower standard when making claims such as “good source” or “high.” For example, by using population-weighted AIs, a company taking the seafood processors’ approach could claim, at the point of sale, that the reference value for ALA is 1.3 g/day, even while companies taking Martek’s approach, which uses the population-coverage approach, are claiming, based on the same IOM report, that the reference value for ALA is 1.6 g/day. Furthermore, on the label of a product that contained 0.3 g of ALA, those taking the seafood processors’ approach would declare the product to be “high” in ALA, because 0.3 g is approximately 23 percent of 1.3 g; however, those taking Martek’s approach would declare an identical product to only be a “good source” of ALA, because 0.3 g is only 18.75 percent of 1.6 g. The presence of these conflicting claims is inherently misleading. More generally, the claim proposed by the seafood processors is inherently misleading in the context of FDA’s current labeling regime, which relies solely on the population-coverage approach, because the seafood processors’ claim would create contradictory information about the meaning of “good source” when used to characterize the level of a nutrient.

Even if a disclaimer or other modification were to explain that a given claim arose as a result of a certain statistical method for computing nutrient levels, this would not change the fact that terms such as “high” or “good source” would have two different meanings under this hypothetical regime. This is precisely what Congress sought to avoid when it passed the NLEA, and it is what we sought to avoid when we issued regulations under that statute, defining terms such as “high” and “good source.” See, e.g., 136 Cong. Rec. H5836-01, H5840 (July 30, 1990) (statement of Rep. Waxman); 136 Cong. Rec. H12951-02, H12953-54 (October 26, 1990)

(statement of Rep. Madigan). (See also 56 FR 60421 at 60423, (November 27, 1991))

(“Inconsistent use of the same term on various products could lead to consumer confusion and nonuniformity in the marketplace. To ensure that consumers are not misled and are given reliable information, Congress found, and FDA agrees, that it is appropriate for the Agency to establish specific definitions to standardize the terms used by manufacturers to describe the nutrient content of foods.”); see also 58 FR 2302. The purpose of FDA-regulated nutrient content claims is to provide the public with meaningful information about the content of a product within the context of the total daily diet. This purpose is only served if terms such as “high,” “good source,” and the other terms defined at § 101.54 (21 CFR 101.54) are given a consistent meaning for all nutrients that are the subject of such claims, so that consumers have meaningful information to compare.

We therefore conclude that the ALA claims that are based on a population-weighted approach are inherently misleading, and thus not entitled to First Amendment protection. But even if the seafood processors’ proposed claims were not inherently misleading, prohibiting the claims would still be permissible under the First Amendment. Though we have concluded that the claims are inherently misleading, this section nonetheless goes on to analyze this point.

In Central Hudson Gas & Elec. Corp. v. Public Serv. Comm’n of New York, 447 U.S. 557 (1980), the Supreme Court laid out a four-part test to analyze whether a Government restriction on commercial speech is constitutional. The first step under Central Hudson is to determine whether or not the speech at issue is protected by the First Amendment. If the speech is found to be protected by the First Amendment--which we do not find to be the case here, but which is a scenario that we are nonetheless analyzing--the second requirement of Central Hudson is that “the State must assert a substantial interest to be achieved” by the proposed action. Central

Hudson, 447 U.S. at 564. Here, the Government has a substantial interest in promoting the public health, preventing inconsistent and contradictory labeling claims (and thereby preventing consumer confusion), and maintaining the integrity of the food label so that consumers will have access to meaningful information that they can understand in the context of a total daily diet and that will enable them to make meaningful product-to-product comparisons so they can select foods that can lead to healthier diets (see Pearson, 164 F.3d at 656; Rubin v. Coors Brewing Co., 514 U.S. 476, 485 (1995); Fleminger v. U.S. Dep’t of Health and Human Servs., 854 F. Supp. 2d 192, 208 (D. Conn. 2012); and 58 FR 2302).

The next question under Central Hudson is whether the government action “directly advances the governmental interest asserted.” Central Hudson, 447 U.S. at 566. The need for consistent labeling claims that would help consumers select healthier foods is the precise issue that Congress sought to address when passing the portions of the NLEA that address nutrient content claims. See, e.g., 136 Cong. Rec. H5836-01, H5840 (July 30, 1990) (statement of Rep. Waxman) (“[Under the NLEA,] content claims would have to be consistent with terms defined by...the Food and Drug Administration. Today, companies use terms such as ‘low’ and ‘light’ differently and inconsistently.... The bill would correct this deceptive and misleading state of affairs by requiring that terms such as ‘light’ have a single meaning.”) and *id.* at H5843 (statement of Rep. Madigan) (“Consumers today are confronted with a variety of labels that provide them with disjointed and confusing information.... In the past few years, important scientific evidence has been repeatedly reported that clearly links dietary habits to good health. For this reason, the need to provide consumers with better information about the foods they eat is important.”); see also 136 Cong. Rec. H12951-02, H12953-54 (October 26, 1990) (statement of Rep. Madigan) (“[T]he bill requires that content claims such as light, low, et cetera, would have

to be consistent with terms defined by the FDA. This is to address the current problem of companies using these terms differently and inconsistently.”). Requiring that all nutrient levels be computed in the same way so that words such as “high” will have a consistent meaning directly advances the goals of preventing inconsistent and contradictory claims in food labeling, maintaining the integrity of the food label, and promoting public health. The result is labels that contain meaningful information that the consumer can understand in the context of a total daily diet. Such labels allow consumers to make meaningful product-to-product comparisons and to select foods that can lead to healthier diets.

The final question under Central Hudson is “whether the fit between the government’s ends and the means chosen to accomplish those ends ‘is not necessarily perfect, but reasonable.’ ” See Pearson, 164 F.3d at 656, quoting Fox, 492 U.S. at 480. The Government’s approach here is narrowly tailored to advance the Government’s interest in preventing inconsistent and contradictory claims, maintaining the integrity of the food label, and promoting the public health, while not unnecessarily infringing speech. Nutrient content claims are not prohibited, but instead are permitted under a range of circumstances. Nutrient content claims based on an authoritative statement may be used, provided that the relevant nutrient reference level is not based on an approach that results in inconsistent and contradictory information. In this situation, we are taking no regulatory action at this time with regard to a nutrient content claim for ALA that uses the population-coverage approach to determine the nutrient level; that claim may therefore be used. The comments have advanced no argument to explain why the use of multiple, inconsistent statistical methods that generate inconsistent and contradictory claims would be preferable for consumers. Such claims would, in fact, impede the ability of consumers to make meaningful product-to-product comparisons, and therefore to make informed purchasing

decisions. We also note that, in addition to the population coverage-based ALA claims about which we are taking no action at this time, other opportunities exist for companies to make labeling statements regarding ALA in their products; for example, labeling that simply states the amount of a nutrient may be made in accordance with § 101.13(i).

Moreover, we have concluded that no disclaimer could cure the fundamental contradiction and inconsistency resulting from the proposed ALA claims that are based on the population-weighted approach. No disclaimer would cure the fundamental flaw presented here: that the use of two different daily values for ALA would render the nutrient content claims that were based on those reference values inconsistent with one another, and would therefore impede consumers' ability to make meaningful product-to-product comparisons based on those claims. A disclaimer cannot bring clarity to a situation where a fundamental contradiction remains. See Resort Car Rental System, Inc. v. FTC, 518 F.2d 962, 964 (9th Cir.) (per curiam), cert denied, 423 U.S. 827 (1975); Continental Wax Corp. v. FTC, 330 F.2d 475, 480 (2d Cir. 1964); United States v. Millpax, Inc., 313 F.2d 152, 154 & n.1 (7th Cir. 1963); Pasadena Research Labs v. United States, 169 F.2d 375, 383-84 (9th Cir. 1948). Labeling that states the amount of a nutrient may be made under § 101.13(i); the purpose of nutrient content claims is to use words such as “high” and “good source,” which, because they are defined by regulation, place that type of information in the context of the total daily diet. This purpose is only served if the terms defined at § 101.54 are given a consistent meaning.

(Comment 4) A number of comments suggested that FDA should establish, through notice and comment rulemaking, DVs for DHA and EPA for use in nutrient content claims and requested that FDA continue to allow the current claims for DHA and EPA until DVs can be established.

(Response) We disagree that we should continue to allow these claims, pending a rulemaking to establish DVs for DHA and EPA, for the reasons set forth in this final rule for prohibiting such claims. Under section 403(r)(4) of the FD&C Act and § 101.69, interested persons can submit a petition for the authorization of nutrient content claims.

(Comment 5) A number of comments stated that we did not respond to the notifications in a timely manner and that, as a consequence, many manufacturers would be affected financially by a prohibition of certain omega-3 nutrient content claims. Several comments stated that there could be a possible negative health impact in removing omega-3 claims that have existed for some time in the marketplace, including increased consumer confusion regarding recommended intakes of omega-3 fatty acids. Other comments requested that, because the omega-3 nutrient content claims have been lawful and in use in the marketplace for some time, FDA should provide a transition period to phase them out (e.g., 1 year) if the Agency decides to prohibit certain omega-3 nutrient content claims.

(Response) We disagree with the comments asserting that we did not act in a timely manner. Section 403(r)(2)(G)(ii) of the FD&C Act, permits a food bearing a nutrient content claim based on an authoritative statement to be introduced into interstate commerce 120 days after notifying FDA. The claim may be made until we issue a regulation prohibiting the claim, modifying the claim, or finding that the requirements of the FD&C Act have not been met, or a district court of the United States determines that the requirements of the FD&C Act have not been met (section 403(r)(2)(H) of the FD&C Act). We received three separate notifications for omega-3 fatty acids over a 2-year period ending in December 2005. Because the notifications addressed the same issue, we conducted a collective review of the notifications and determined that all three notifications should be addressed in the same rulemaking, rather than separately. In

June 2004, we publicly announced our intention to issue rulemaking to prohibit some of the nutrient content claims (see Docket No. FDA-2004-N-0382) (Ref. 4) and, less than 2 years after the receipt of the final notification, we issued the proposed rule.

We agree with the comments requesting a transition period. In this final rule, we conclude that certain omega-3 fatty acid nutrient content claims set forth in the three notifications do not meet the requirements of section 403(r)(2)(G) of the FD&C Act and, therefore, are prohibited from use in food labeling. We are providing a period for transition, and this rule will become effective on the next uniform compliance date for labeling regulations. The next uniform compliance date is January 1, 2016, and it applies to food labeling regulations issued between January 1, 2013, and December 31, 2014.

III. Summary of the Final Rule

Given the information discussed in the preamble to the omega-3 proposed rule and the absence of contrary information in the comments, and under our authority under section 403(r)(2)(H)(i)(I) of the FD&C Act, FDA is adopting as a final rule, without change, the proposal to prohibit the nutrient content claims for DHA and EPA set forth in the seafood processors notification, the Martek notification, and the Ocean Nutrition notification and the nutrient content claims for ALA set forth in the seafood processors notification. We express no conclusions as to whether the ALA claims in the Martek notification are supported by an authoritative statement that satisfies the requirements of section 403(r)(2)(G) of the FD&C Act. We are taking no regulatory action at this time with respect to the nutrient content claims for ALA set forth in the Martek notification and, therefore, these claims, which are set forth in table 1, will be allowed to remain on the market at this time.

Table 1.-Nutrient Claims

Nutrient Content Claim for ALA	Conditions For Making the Claim ¹
High	≥ 320 mg of ALA per RACC (≥ 20% of 1.6 g/day)
Good Source	≥ 160 mg of ALA per RACC (≥ 10% of 1.6 g/day)
More	≥ 160 mg of ALA more per RACC than an appropriate reference food (≥ 10% of 1.6 g/day)

¹ Nutrient content claims must comply with all applicable FDA regulations regarding the making of such claims.

IV. Analysis of Impacts

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104-4). Executive Order 12866 directs Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We have concluded that this final rule is not a significant regulatory action under the Executive order.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. We have concluded that this final rule may have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$141 million, using the most current (2012) Implicit Price

Deflator for the Gross Domestic Product. We do not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

This final regulatory impact analysis revises the initial regulatory impact analysis set forth in the proposed rule (72 FR 66103) in response to comments on the proposed rule. Except for the revisions that we indicate in this section of the document, the analysis for the final rule is the same as the analysis for the proposed rule.

A. Benefit-Cost Analysis

1. The Need for This Rule

We discuss any comments on the legal and regulatory need for this rule in section II of this document.

2. Options

In the analysis for the proposed rule, we analyzed the following two regulatory options: (1) Take no new regulatory action and (2) prohibit the DHA and EPA claims and the ALA claims based on a reference value of 1.3 g/day, but allow the ALA claims based on a reference value of 1.6 g/day.

a. Option 1: Take No New Regulatory Action.

We did not receive any comments on the selection of this option as the baseline.

b. Option 2: Take the Regulatory Actions as Described in the Proposed Rule.

(Comment 6) One comment asserted that the economic analysis for the proposed rule did not fulfill the requirements of Executive Order 12866 because we said that we could not estimate the public health impacts of eliminating nutrient content claims for DHA and EPA because we had not yet conducted a review of the scientific evidence concerning the health effects of consuming DHA and EPA at various levels. The comment suggested that we review the relevant

scientific evidence to complete the analysis. The comment also noted that we previously reviewed at least some of the scientific evidence relating to cardiovascular effects in the context of qualified health claims for DHA and EPA. The comment said that, on that basis alone, FDA could present a more detailed analysis of potential health costs than it presented in the analysis for the proposed rule.

Other comments said that eliminating existing nutrient content claims for DHA and EPA would generate public health costs. These comments linked DHA and/or EPA to preventing cardiovascular disease, reducing cardiac mortality including sudden death in patients with no sign of cardiovascular conditions and cardiovascular events in hypercholesterolemic patients, growth, neurodevelopment including brain and eye development in infants, intelligence quotients, and improved mental acuity and overall quality of life for consumers facing age-related cognitive decline, including Alzheimer's disease. The comments also noted possible links to the prevention and treatment of arthritis, inflammatory and autoimmune diseases, and cancer. One comment noted that current average intake of DHA and EPA is estimated to be 100 to 200 mg/day in the United States, which is below the intake recommended by various organizations.

(Response) In the analysis for the proposed rule, we said that we could not determine whether eliminating existing nutrient content claims for DHA and EPA would have any impact on consumer health because we had not yet conducted a review of the scientific evidence on the health effects of consuming DHA and EPA at different levels. The information presented in these comments suggests that eliminating nutrient content claims for DHA and EPA could lead to health costs. However, because we have not yet conducted a comprehensive review of the scientific evidence, we cannot revise the analysis of the final rule to account for these potential effects.

(Comment 7) A number of comments addressed the relative merits of nutrient content claims, qualified health claims, and quantitative statements. One comment stated that qualified health claims are a poor substitute for nutrient content claims and that eliminating nutrient content claims would reduce opportunities for firms to communicate with consumers about EPA and DHA. The comment looked at health claims appearing on new omega-3 fatty acid and DHA and/or EPA products in the Mintel Global New Products Database between June 2006 and November 2007 and found that 24 percent were nutrient content claims, 56 percent were quantitative statements, and 20 percent were structure function claims. The comment suggested that nutrient content claims and quantitative statements predominated because they are relatively simple and easy to understand. One comment said that qualified health claims and quantitative statements do not enable consumers to consider the relative significance of the claims and statements in the context of the total daily diet. This comment said that without nutrient content claims, consumers would be unable to determine if quantitative content differences are significant or to readily identify foods that contain meaningful levels of omega-3 fatty acids. Finally, the comment noted that removing nutrient content claims would significantly diminish the incentives for firms to innovate and to improve the nutritional properties of food. One comment noted that we permit qualified health claims on products regardless of the level of DHA or EPA in those products. The comment said that we did not consider the potential health costs generated by consumers switching to products having potentially lower levels of DHA and/or EPA. One comment said that prohibiting DHA and EPA claims after they have appeared for several years would lead consumers to question the dietary value of these nutrients. One comment said that allowing quantitative statements about the level of DHA and/or EPA in

products without providing some context of the significance of those levels would confuse consumers.

(Response) Our analysis for the proposed rule did not claim that the availability of qualified health claims implied that eliminating nutrient content claims for DHA and EPA would have no impact on product innovation, consumption of these substances, or consumer health. We said that eliminating nutrient content claims for DHA and EPA might result in reduced consumption of DHA and EPA under two scenarios. First, consumers might reduce their consumption of these nutrients if they choose not to purchase and consume products that do not have the relevant nutrient content claims on the label. Second, producers may choose not to reformulate products with higher levels of DHA and/or EPA if they cannot use nutrient content claims to communicate these higher levels to consumers. However, we did not consider potentially reduced consumption resulting from the following mechanisms discussed in some comments: consumers switching to products with qualified health claims that may have lower levels of DHA and/or EPA, consumers who choose not to consume products with DHA and/or EPA because they question the dietary value of these nutrients due to the disappearance of nutrient content claims, and consumers who become confused about the significance of particular levels of DHA and EPA due to the disappearance of nutrient content claims. Therefore, we revise our analysis to include these additional pathways by which this final rule may reduce consumption of omega-3 fatty acids, but we still reach the same conclusion: Because we have yet to conduct a review of the scientific evidence concerning the health effects of consuming EPA and DHA at different levels, we cannot determine whether the loss of these claims would have any impact on consumer health, either beneficial or detrimental.

(Comment 8) Some comments said that FDA did not present a statistically representative portrait of the number of products containing DHA and/or EPA and instead relied on products that we found in grocery stores in the Washington, DC metropolitan area and on Internet grocery stores.

(Response) We did not present our estimates in the analysis for the proposed rule as a statistically representative portrait of the number of products containing DHA and/or EPA. Constructing a statistically representative portrait would be very costly and would not be worthwhile because it would not change the conclusions of the analysis. We have estimated that this rule will generate very small costs that are considerably below the cutoff for classifying a rule as significant under Executive Order 12866, so performing a statistically representative study would probably not change the status of this rule under that Executive Order. In addition, we were unable to quantify benefits, so obtaining more precise cost estimates would not allow the Agency to revise its analysis of net benefits.

(Comment 9) One comment said that we only considered seafood, eggs, pasta, and dietary supplement products, and we excluded many of the emerging categories of foods that firms enrich with omega-3 fatty acids. The comment said that these emerging categories are categories that contain foods that traditionally do not contain omega-3 fatty acids. According to this comment, food manufacturers tend to rely heavily on nutrient content claims to communicate the benefits of DHA and EPA enrichment over other products within these categories. The comment stated that some of these categories include fresh and shelf-stable milks, spoonable yogurts, yogurt drinks, fermented milk drinks, cheeses, butters, fat-based spreads, juices, juice smoothies, soy milks, packaged breads, meats from grass-fed animals, packaged meats, baby foods, chocolate confections, cooking oils, packaged soups, ice creams,

nutritional bars, and frozen pizzas. One comment said that firms are currently making nutrient content claims involving ALA, DHA, and EPA on dairy products. The comment said that we did not account for the costs associated with these products in the analysis for the proposed rule. One comment stated that we underestimated the number of products and labels affected by the proposed rule. The comment noted that, in the analysis for the proposed rule, we said that we found 113 qualifying dietary supplements in the Dietary Supplements Sales Information database, but that when we searched a single retailer, Amazon.com, we turned up 2,224 dietary supplement labels (stock keeping units or SKUs) containing “fish oil.” The comment said that we also underestimated the number of SKUs for eggs and seafood.

(Response) We were unable to locate information on products bearing omega-3 nutrient content claims in the specific product categories mentioned in this comment. However, we did locate data indicating that firms introduced 369 new food and beverage products bearing omega-3 claims in the United States from 1999 to 2014 (Ref. 5). We do not know how many of these products remain on the market, nor do we know how many of these products bear one or more of the relevant nutrient content claims. Therefore, this number represents the maximum number of such products currently on the market.

In the preamble to the proposed rule, we identified only one conventional food product that firms enriched with omega-3 fatty acids. We estimated that two such products probably existed on the market, and estimated a label change cost of \$17,000, or \$8,500 per product. If we apply this cost to 369 products, we get an estimated cost of approximately \$3 million. Therefore, in this final rule, we have revised the previous estimate of the total cost of labeling changes from \$0.08 million to approximately \$3 million.

(Comment 10) One comment said that firms launched a significant number of products enriched with DHA and EPA in part because they were able to communicate some of the benefits of DHA and EPA using nutrient content claims. This comment said that we did not consider the loss of sales that would result if these firms were unable to communicate the relative enrichment levels of DHA and EPA in these products, but that we instead only considered the cost of relabeling these products. One comment stated that we did not account for the loss of the return on investment in product development.

(Response) Once the final rule becomes effective, firms will retain some ability to communicate levels of omega-3 fatty acid content to consumers by using amount or percentage statements and qualified health claims. These statements might not be as effective as express nutrient content claims (e.g., “high”) in encouraging consumers to buy these products. Therefore, sales of these products and the return on investment for developing these products may decline. We would classify these effects as distributive impacts rather than social costs because we have based our rule on the notion that these nutrient content claims lack the scientific support that an authoritative statement would provide. Therefore, consumer demand based on these nutrient content claims does not represent the true demand for these products and prohibiting these nutrient content claims will not generate social costs for consumers. However, some firms may lose sales and profits and some firms may gain sales and profits. We cannot estimate this distributive impact because we do not know how much money firms have spent developing these products or the impact of eliminating nutrient content claims for DHA and/or EPA on the sales of these products. However, we revised the analysis by noting that firms that produce products or that planned to produce products bearing these nutrient content claims may lose profits, while firms producing competing products may gain profits.

(Comment 11) One comment said that we were rejecting the nutrient content claims presented in the seafood processors notification based on our approach to calculating a nutrient reference value. This comment noted that we had published the DV ANPRM (72 FR 62149) inviting comments on what new reference values we should use to calculate the DVs in the Nutrition Facts label and what factors we should consider in establishing such new reference values. The comment noted that if we change our position on setting reference values, then we might need to reverse our position on the nutrient content claims in the seafood processors notification, which would generate additional label changes and also confuse consumers.

(Response) Even if we were to establish, in the future, a population-weighted approach for DVs that would allow the nutrient content claims in the seafood processors notification and thus allow firms to make additional label changes, we can infer that any such label changes would be associated with positive net benefits. Firms that were using the nutrient content claims in the seafood processors notification and that stopped using those claims because of this final rule might be able to resume using those claims. However, because such label changes would be voluntary, manufacturers would not choose to make them unless consumers valued the changes at least enough to cover the cost of such changes. Manufacturers are not likely to voluntarily make nutrient content claims if the addition would confuse consumers and negatively impact sales. We would not allow such label changes if we determined them to be false or misleading; therefore, we would infer that any additional value consumers placed on such products is related to the value of the new information. In addition, changes in product labeling are not particularly unusual, so it is unlikely that many consumers would be confused if the nutrient content claims on particular products disappeared and later reappeared.

(Comment 12) One comment said that a single label change can cost dairy processors up to \$5,000 per label for a new label design and new printing plates. The comment noted that firms would also need to dispose of obsolete packaging and that, in the past, companies have estimated these costs in the tens to hundreds of thousands of dollars, depending on the number of SKUs.

(Response) In the analysis for the proposed rule, we estimated the cost of changing labels using a model developed for us for that purpose. The model included designing new labels, producing new printing plates, and disposing of obsolete packaging. We estimated costs per SKU of between \$2,300 and \$8,400. This figure implies that a large company producing many SKUs could face costs of tens to hundreds of thousands of dollars for disposing of obsolete packaging. Therefore, this comment is consistent with the analysis for the proposed rule.

B. Benefits

(Comment 13) One comment said that there is no scientific evidence supporting health benefits of 160 mg of DHA and/or EPA per day but that, on the contrary, the science supports much higher levels. This comment said that to allow the use of an “excellent source” claim for this level of these nutrients might cause consumers to lose confidence in package claims.

(Response) Some consumers may have experienced a reduction in their confidence in package claims based on the discrepancy between nutrient content claims describing products with 160 mg of DHA and/or EPA as an excellent source of these nutrients and the level of these nutrients recommended by some scientific organizations. These consumers may experience increased confidence in package claims when this discrepancy is eliminated. Increased confidence in package claims could lead to health benefits from better dietary choices based on package claims. We do not have sufficient information to estimate this potential benefit.

C. Regulatory Flexibility Analysis

We have examined the economic implications of this final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601-612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires Agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities. We find that this final rule may have a significant economic impact on a substantial number of small entities.

The Regulatory Flexibility Act requires that FDA present a succinct statement of a rule's objectives. We discussed the legal and regulatory need for this rule in section II of this document and in section III in the preamble of the proposed rule (72 FR 66103 at 66107). The intent of this rule is to eliminate certain nutrient content claims that do not have the scientific justification that an authoritative statement would provide or that are not stated in a manner that enables the public to comprehend the information provided in the claim and to understand the relative significance of the information in the context of a total daily diet. In so doing, the rule enables consumers to identify suitable products.

In the analysis for the proposed rule, we said that the proposed rule would not have a significant effect on a substantial number of small entities. We based that conclusion on our review of the labels in the marketplace. However, one comment on the benefit-cost analysis in the proposed rule suggested that we had overlooked a number of products. Based on that comment, we estimated a new range of potentially affected products in the final benefit-cost analysis. The new range of potentially affected products suggests that the final rule might have a significant effect on a substantial number of small entities.

In the benefit-cost analysis for this rule, we estimated that the final rule would affect a maximum of 369 products. We were not able to identify the firms that produce these products. However, in the analysis for the proposed rule, we estimated that four products were associated with four manufacturers. Therefore, we assume that 369 products may be associated with 369 manufacturers. We also were not able to identify these products, although the comments indicated that they include products from the following categories: seafood, pasta, eggs, fresh and shelf-stable milks, spoonable yogurts, yogurt drinks, fermented milk drinks, cheeses, butters, fat-based spreads, juices, juice smoothies, soy milks, packaged breads, meats from grass-fed animals, packaged meats, baby foods, chocolate confections, cooking oils, packaged soups, ice creams, nutritional bars, and frozen pizzas.

The Small Business Administration (SBA) publishes size standards for small businesses. The SBA size definition for firms producing these products defines a small firm to be any firm with 500 or fewer employees. We do not know how many employees work at the firms that produce the specified products because we cannot identify those firms. However, the vast majority of these firms probably meet the SBA definition of a small business because nearly all (97 percent) of food manufacturing plants have 500 or fewer employees.

1. Options

FDA considers the following option to reduce the burden of this rule on small entities: give small firms more time to comply with this rule.

Option 1: Give small firms more time to comply with this rule.

This rule will become effective on the next uniform compliance date for labeling regulations. The next uniform compliance date is January 1, 2016, and it applies to food labeling regulations that FDA issues between January 1, 2013, and December 31, 2014. Using the next

uniform compliance date always provides firms with at least 1 year and as much as 3 years to make any necessary labeling changes. In the analysis for the proposed rule (72 FR 66103 at 66109), we based our cost estimates on firms having 2 years to change product labels. Providing more time to change labels reduces the cost of changing those labels because more firms would be able to make the changes during regularly scheduled label changes. In the analysis for the proposed rule, we noted that our labeling cost model estimates that firms will redesign 67 percent of product labels in any 2-year period and all product labels in any 3-year period. Therefore, if we changed the compliance date for small firms so that they had at least 3 years to comply, then we would reduce the cost for these firms to zero. To avoid inconsistent labeling on products produced by small firms and by other firms, we would need to set the same compliance date for all firms. This option would delay the benefits of this rule. Therefore, we have chosen not to give small firms more time to comply with the final rule.

V. Environmental Impact

We have determined under 21 CFR 25.30(k) that this action is of the type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Paperwork Reduction Act of 1995

We conclude that labeling provisions of this rule are not subject to review by the Office of Management and Budget because they do not constitute a “collection of information” under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

VII. Federalism

We analyzed this final rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive order requires Agencies to “construe...a Federal statute to

preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State law conflicts with the exercise of Federal authority under the Federal statute.” Federal law includes an express preemption provision that preempts “any requirement respecting any claim of the type described in section 403(r)(1) [21 U.S.C. 343(r)(1)] made in the label or labeling of food that is not identical to the requirement of section 403(r) [21 U.S.C. 343(r)]....” Section 403A(a)(5) of the FD&C Act (21 U.S.C. 343-1(a)(5)). However, this statutory provision does not preempt any State requirement respecting a statement in the labeling of food that provides for a warning concerning the safety of the food or component of the food (Pub. L. 101-535, Section 6 (1990)). This final rule prohibits certain nutrient content claims for certain omega-3 fatty acids in the label or labeling of food under section 403(r) of the FD&C Act.

VIII. References

The following references have been placed on display in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852 and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at <http://www.regulations.gov>. (FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to Web sites after this document publishes in the Federal Register.)

1. “Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids.” Institute of Medicine, National Academy of Sciences, 2005.

2. Letter from the Institute of Medicine of the National Academies to FDA/CFSAN. Docket No. FDA-2004-N-0382; Document ID FDA-2004-N-0382-0035.

3. “Dietary Reference Intakes: Guiding Principles for Nutrition Labeling and Fortification.” Institute of Medicine, National Academy of Sciences, 2003.

4. Letter from FDA/CFSAN to Advocates for Better Children's Diets. Docket No. FDA-2004-N-0382; Document ID FDA-2004-N-0382-0004.

5. Data from Mintel Global New Products Database, Mintel Group, Ltd., <http://www.mintel.com/>, accessed January 29, 2014.

Dated: April 22, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-09492 Filed 04/25/2014 at 8:45 am; Publication Date: 04/28/2014]